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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/923,122	08/06/2001	Gilberto Bestetti	6330.01	9725
7.	590 06/23/2004		EXAM	INER
DAVID E. BRUHN			HAYES, MICHAEL J	
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT			ART UNIT	PAPER NUMBER
SUITE 1500, 50 SOUTH SIXTH STREET			3763	
MINNEAPOLIS, MN 55402-1498			DATE MAIL ED. 06/22/2004	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		$\mathcal{A}$				
	Application No.	Applicant(s)				
	09/923,122	BESTETTI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Michael J Hayes	3763				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be to within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONI	imely filed  ys will be considered timely.  In the mailing date of this communication.  ED (35 U.S.C. § 133).				
Status	•					
1) Responsive to communication(s) filed on 29 M	<u>arch 2004</u> .					
,	2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.					
	,— , ,					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	.53 O.G. 213.				
Disposition of Claims						
4) ☐ Claim(s) 20-29 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 20-29 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.					
Application Papers	·					
9)☑ The specification is objected to by the Examine 10)☑ The drawing(s) filed on 06 August 2001 is/are:  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the Ex	a) $\square$ accepted or b) $\boxtimes$ objected drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	ee 37 CFR 1.85(a). pjected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicat ity documents have been receiv ı (PCT Rule 17.2(a)).	tion No. <u>09/048682</u> . red in this National Stage				
Attachment(s)	4) 🖂 Intention Summer	(DTO 442)				
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summan Paper No(s)/Mail D 5) Notice of Informal I 6) Other:					

#### **DETAILED ACTION**

### **Drawings**

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the anchoring plate extending from the shaft as recited in claim 21 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The drawings show the anchoring plate extending from the lower fin.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### Specification

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For

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benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.

" should follow the filing date of the parent application.

# Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant recites the anchoring plate extending from the shaft, but has previously only shown the anchoring plate extending from the lower fin (see fig. 1). It appears that this new limitation concerning the anchoring plate position is new matter.

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# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by BENTLEY et al. (US Patent No. 4183357). Bentley discloses an implantable device having a shaft, radial and anchoring fins forming a rounded cross-sectional pocket 58. See fig. 5.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY as applied to claim 25 above, and further in view of BOKROS (US Patent No. 3783868). Bentley discloses the claimed invention except for a disc-shaped anchoring plate around the shaft with an anchoring fin. Bokros teaches a disc-shaped anchoring plate 26 around a shaft with an anchoring fin 52 protruding therefrom. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bokros in the invention of Bentley in order to provide anchoring structure to prevent unwanted movement of the implantable device.

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### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 17, 19-24 of U.S. Patent No. 6,270,475. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite an access port with fins having edges closer than a diameter of a formed channel and an anchoring plate that curves along its radial extent.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh 21 June 2004

> MICHAEL J. HAYES PRIMARY EXAMINER

m/ Hayes